

REMARKS***Status of the claims***

Claims 1-6, 11, 14-59, 62, 63 and 65-99 are pending in this application. Of the above claims 1-5, 20-37, 39, 40, 42, 43, 46-56, 67 and 68 have been withdrawn from consideration as drawn to a nonelected invention. Claims 6, 11, 14-18, 38, 57-59, 62, 63, 65, 66, 70-75, 79-88 and 90-98 are allowed, and claims 19, 41, 44, 45, 69, 76-78, 89 and 99 are rejected. By virtue of this amendment, claims 19, 69, 76, 77, 78, 79, and 89 have been amended and claims 41, 44, 45, 66, and 99 have been canceled.

Support for the amendments to claims 19, 69, 77, and 89 may be found, for example, on page 15, lines 34-38, of the specification. Claims 78, 79, and 89 have been amended solely to remove dependency on canceled claims. No new matter has been added by the foregoing amendments.

Applicants acknowledge with appreciation the withdrawal of rejections not reiterated in the present Office Action.

With respect to all amendments and canceled claims, Applicants have not dedicated to the public or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional applications.

Rejections under 35 U.S.C. §101

Claims 19 and 77 are rejected under 35 U.S.C. §101 as allegedly directed to non-statutory subject matter. The Examiner states that “[t]he claims are broadly interpreted to

encompass host cells, which are not isolated and are comprised within an organism.” Applicants respectfully traverse this rejection.

Prokaryotic and eukaryotic host cells are described in the specification as “transformed with (*i.e.*, comprising) 11D10 polynucleotides and/or vectors having 11D10 polynucleotide(s) sequences.” Page 36, lines 16-17. Therefore, by definition, host cells are not naturally occurring since they are *transformed* with an exogenous polynucleotide. The Examiner states that the description at page 36, lines 26-27, of the specification, that “host cells may also be used as vehicles for *in vivo* delivery of 11D10 polypeptides,” indicates that the host cells may be comprised within a transgenic animal, including a human, which is non-statutory subject matter. Applicants respectfully note that claims at issue are directed to host cells. Although a host cell could be comprised within a human being, this does not mean that the claims are directed to non-statutory subject matter. By analogy, a medical device may be comprised within a human being, but this does not render the medical device itself non-statutory subject matter. The specification discloses a *utility* for the claimed host cells as vehicles for *in vivo* delivery of polynucleotides. However, the *claims* are directed only to the host cells.

Although Applicants do not agree with or acquiesce in the rejection, claims 19 and 77 have been amended to recite “isolated,” solely to expedite prosecution, thereby obviating the rejection.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of rejection under 35 U.S.C. §101.

Claims 41, 44, 45, and 99 are rejected under 35 U.S.C. §101 as allegedly not supported by a specific and substantial, credible, or well-established utility. Applicants respectfully traverse this rejection.

Immunogenic compositions comprising a polynucleotide as claimed and a pharmaceutically acceptable excipient are described on page 54, line 5 - page 55, line 27 of the specification. Disclosed utilities include, for example, elicitation of a protective immune response

by introduction of the claimed polynucleotides into host cells or vectors, such as plasmid expression vectors or viral vectors, for use as a vaccine.

Although Applicants do not agree with or acquiesce in the rejection, as discussed above, claims 41, 44, 45, and 99 have been canceled solely to expedite prosecution, rendering the rejection moot.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §101.

Rejections under 35 U.S.C. §112, first paragraph

Claims 41, 44, 45 and 99 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement because the claimed invention is allegedly not supported by a specific and substantial asserted utility, a credible asserted utility, or a well-established utility. Applicants respectfully traverse this rejection.

As discussed above, utilities such as, for example, vaccines for elicitation of a protective immune response, are described in the specification for the claimed immunogenic compositions. Methods for making and using the immunogenic compositions are described on page 54, line 5 - page 55, line 27 of the specification. Thus, the specification provides support for both utility and enablement of the claimed invention. However, without acquiescence to the rejection, and solely to expedite prosecution, claims 41, 44, 45, and 99 have been canceled, rendering the rejection moot.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Claims 19, 69, 77, and 89 are rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled. The Office Action states that the specification, while being enabling for making and using an isolated host cell, does not reasonably provide enablement for any host cell encompassed by the claims. Applicants respectfully traverse this rejection.

The specification describes how to make and use the claimed host cells without undue experimentation. Host cells are described in the specification as prokaryotic and eukaryotic cells that have been transformed with 11D10 polynucleotides and/or vectors having 11D10 polynucleotide sequences. Page 36, lines 16-17. Methods for such transformation are well known in the art, and are described in the specification on page 33, lines 28-35. Methods for expression of recombinant polynucleotides in host cells are also well known in the art, and are described in the specification, for example, in Example 2. Thus, the claimed host cells are enabled by the specification. Since such methods are well known in the art, no undue experimentation would be required to make and use the claimed host cells for production of 11D10 polynucleotides.

Although Applicants do not agree with or acquiesce to the rejection, as discussed above, and solely to expedite prosecution, claims 19, 69, 77, and 89 have been amended to recite "isolated" host cells, which the Examiner states will obviate the rejection.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. §112, second paragraph

Claims 76 and 78 are rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite because they depend from canceled claims. The claim dependency in claims 76 and 78 has been amended to delete dependency from canceled claims, thus rendering the rejection moot.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Double Patenting

The Office Action states that the subject matter of the pending claims is allowable, provided that Applicants timely file a terminal disclaimer.¹ However, in a telephone call on April 21, 2004, Examiner Rawlings indicated that the double patenting rejection has been withdrawn and that it is not necessary for Applicants to file a terminal disclaimer.

¹ This statement on page 9 of the Office Action contradicts a statement on page 3 of the Office Action that “[t]he obviousness type double patenting rejection has been withdrawn in view of the restriction set forth in the Office action mailed September 4, 1998 between claims drawn to a nucleic acid molecule encoding a protein and claims drawn to the protein.” Applicants respectfully note that the previous double patenting rejection in this case was made in view of U.S. Patent No. 6,274,143, which was not subject to a restriction requirement with respect to the present case. However, as discussed above, Examiner Rawlings indicated by telephone on April 21, 2004, that the double patenting rejection has been withdrawn.

CONCLUSION

Applicants have, by way of the amendments and remarks presented herein, removed the issues for the rejections and addressed all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 304142000322. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 17, 2004

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